UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
v.	)	No. 17-cr-10288-WGY
AEGERION PHARMACEUTICALS, INC.,	)	
Defendant.	)	

GOVERNMENT'S SENTENCING MEMORANDUM
(HEARING REQUESTED)

Aegerion Pharmaceuticals, Inc. ("Aegerion") intends to plead guilty to two counts of misdemeanor misbranding of its drug, Juxtapid, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), under the terms of a plea agreement governed by Federal Rule of Criminal Procedure 11(c)(1)(C). The plea agreement includes a sentence of a fine and forfeiture of $7.2 million (plus interest) and a three- to five-year term of probation with terms including an anti-disparagement provision. The United States submits that the proposed sentence is sufficient, but not greater than necessary, to punish Aegerion, to promote respect for the law, to protect the public, and to provide general deterrence, in light of the following facts:

First, long before it entered into the plea agreement, Aegerion purged the corporate executives most responsible for the company's criminal conduct. Aegerion eventually eliminated the sales organization it had during the period of the charged criminal conduct. Significantly, Aegerion's financial condition deteriorated markedly as the company came into compliance with the Federal Food, Drug, and Cosmetic Act. Aegerion also provided, and continues to provide, significant cooperation with the government's ongoing investigation.[1] In short, Aegerion's decision

[1] Details regarding this cooperation are set forth in the United States' sealed *ex-parte* filing to which the defendant assented.

to plead guilty results from a corporate determination to root out the criminal sales and marketing of Juxtapid and to assist the United States in identifying and prosecuting those responsible for it.

Second, to ensure strict compliance with federal law governing sales of Juxtapid, Aegerion has entered, or will soon enter into, agreements with the U.S. Department of Health and Human Services, Office of Inspector General, and a Consent Decree to be monitored by the Food and Drug Administration ("FDA"). Aegerion also has entered a three-year Deferred Prosecution Agreement ("DPA") with the United States and has admitted, in detail, to a corporate conspiracy to violate the Health Insurance Portability and Accountability Act ("HIPAA").

Third, despite its precarious financial condition, Aegerion has agreed not only to pay a criminal fine and forfeiture of $7.2 million but also to pay $28 million (plus interest) to resolve a parallel *qui tam* action, *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc.*, No. 13-cv-11785-IT (D. Mass.). The resulting civil resolution provides restitution to federal programs harmed by Aegerion's sales practices.

Fourth, Aegerion's drug, Juxtapid, notwithstanding the criminal conduct charged in the Information, is one of the few cholesterol-lowering drugs indicated for patients who have homozygous familial hypercholesterolemia ("HoFH"), a rare genetic disease inherited from both parents. Public policy weighs in favor of ensuring an uninterrupted supply of the drug to high-risk patients who actually need it.

Aegerion thus fits in a very narrow category. It is taking responsibility for its crimes and paying penalties at the upper limit of its ability to pay and yet survive as a business. Aegerion has changed course and is helping the United States continue its investigation, thus far, without reservation or hesitation. As explained further below, the proposed sentence therefore satisfies the requirements of 18 U.S.C. § 3553, and the United States requests that the Court accept Aegerion's proffered guilty plea pursuant to the Rule 11(c)(1)(C) plea agreement.

BACKGROUND

I. The Development of Juxtapid (Lomitapide)

Aegerion's drug, Juxtapid (generic: lomitapide) inhibits the production of low-density lipoprotein cholesterol, often called the "bad" cholesterol" due to its association with cardiovascular disease. Liver toxicity is a serious potential side effect of Juxtapid use, and Juxtapid can also cause severe gastrointestinal distress.

In 2007, Aegerion obtained the rights to develop the drug from the University of Pennsylvania. The lead researcher at the University of Pennsylvania, who continued to work with Aegerion to get the drug approved, had previously discussed development of the drug for treatment of severe, refractory hypercholesterolemia. The FDA told him that such a broad indication would require a larger clinical study. As a result, by 2007, development of the drug focused on HoFH, a very rare genetic disease inherited from both parents and characterized by exceedingly high untreated cholesterol levels and early onset cardiovascular disease, often in childhood.[2] In 2009, however, Aegerion again asked the FDA whether it could develop the drug more broadly for treatment of high cholesterol in patients with HoFH *and* with refractory heterozygous familial hypercholesterolemia ("HeFH"), a typically less severe form of hypercholesterolemia than HoFH that is inherited from only one parent. The FDA told Aegerion that such an expanded indication

[2] Aegerion's publicly available submission to an FDA advisory committee in October 2012 states: "As a direct consequence of absent or severely reduced LDL receptor function leading to markedly elevated LDL-C blood levels, patients with HoFH develop dramatically early and severe atherosclerotic CVD [cardiovascular disease] and often, early cardiac-related death. Symptomatic CVD often presents during the first 2 decades of life, and includes atherosclerosis in the coronary arteries, the carotid arteries, the aorta and aortic valve, and the peripheral vasculature, often leading to heart attack, stroke, and death. Early onset of atherosclerosis is generally accompanied by accelerated disease progression, even in the early teenage years. If untreated, most HoFH patients do not survive past age 30 due to death from CVD" (citations omitted). Aegerion Pharmaceuticals, Inc., Sponsor's Background Package, NDA #203858 (available at https://wayback.archive-it.org/7993/20170405220241/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM323843.pdf.

would require additional clinical study. By 2010, Aegerion told the FDA it would only seek approval for HoFH, due to financial constraints. In June 2011, the FDA agreed that Aegerion's existing 29-person clinical study was sufficient for potential approval for treatment of high cholesterol in HoFH patients, if Aegerion defined its target HoFH population by the restrictive inclusion criteria for its existing clinical study and did not use a broader definition that bled into the HeFH population. Aegerion agreed, and after an advisory committee review in October 2012, the FDA approved Juxtapid only for HoFH patients. The FDA also required Aegerion to implement a Risk Evaluation Mitigation Strategy ("REMS") that required physician education and sought to restrict off-label use by, among other things, requiring doctors to attest that their patients' diagnoses were consistent with HoFH.

II. Aegerion's Sales and Marketing of Juxtapid

Aegerion began selling Juxtapid in January 2013. It employed sales representatives nationwide and distributed Juxtapid through a single specialty pharmacy. The initial list price for the drug was roughly $295,000 per patient per year. It increased substantially thereafter.

As detailed in the Information, soon after the FDA approved Juxtapid, Aegerion's then-existing sales management implemented a commercial strategy aimed at blurring the definition of HoFH to include not only HeFH but also treatment-resistant high-cholesterol generally. Aegerion focused not on academic lipidologists familiar with HoFH, but instead on community cardiologists who do not typically treat rare genetic diseases. Aegerion's sales force communicated a misleading commercial message regarding the appropriateness of Juxtapid for treating patients not diagnosed with HoFH, whose clinical profiles did not align with any established, published, peer-reviewed diagnostic criteria for HoFH. In so doing, Aegerion caused the distribution of Juxtapid for the treatment of general hypercholesterolemia, often based on the factually unsupported claim that use of Juxtapid could reduce patients' risk of heart attack or stroke—all despite the warning on

Juxtapid's label that "[t]he effect of JUXTAPID on cardiovascular morbidity and mortality had not been determined." As further charged in the Information, Aegerion's sales and marketing strategies also failed to comply with Aegerion's obligations under the Juxtapid REMS program, which was designed specifically to educate prescribers about the risks of liver toxicity and to restrict access to Juxtapid only to those patients with a clinical or laboratory diagnosis consistent with HoFH.

Misconduct by Aegerion's sales personnel was not limited to the crimes charged in the Information. As Aegerion has admitted in connection with its DPA with the United States, Aegerion, by and through its sales management and sales force, conspired to violate HIPAA by gaining unauthorized access to individually identifiable health information held by HIPAA-covered entities, all for the purpose of marketing Juxtapid for Aegerion's commercial advantage.

Notably, the criminal activity by Aegerion's sales personnel appears to have been in defiance of the training and compliance efforts of Aegerion's legal and compliance officers and contrary to the views and opinions of Aegerion's scientific personnel.

III. Aegerion's Cooperation

The United States understands that, although the government's investigation was a matter of public record as early as January 2014, the Aegerion Board of Directors only fully became aware of the details of the investigation in early 2015. At that time, Aegerion conducted a new internal investigation. In late summer 2015, Aegerion removed its senior management. In September 2015, Aegerion informed the government that it would cooperate with the ongoing investigation. By early 2016, new senior management was in place at Aegerion, and the company informed the government that, in addition to cooperating with the United States' investigation of individuals, Aegerion would plead guilty to charges under the Federal Food, Drug, and Cosmetic Act. Aegerion has cooperated with the government substantively and consistently since that time.

IV. The Global Resolution

By late spring 2016, Aegerion's new management realized that its financial condition was deteriorating. The company requested a global resolution of all outstanding investigations, including the Department of Justice's criminal and civil False Claims Act investigations and the Securities and Exchange Commission's ("SEC") parallel investigation.

The United States demanded, at a minimum, guilty pleas to the core criminal conduct, admissions as to the HIPAA violations, and extensive compliance oversight through a Corporate Integrity Agreement and a Consent Decree to be monitored by the FDA. The resulting global resolution includes: (a) guilty pleas to misdemeanor misbranding charges; (b) a DPA on a conspiracy to violate HIPAA (before Judge Richard Stearns in *United States v. Aegerion Pharmaceuticals Inc.*, No 17-cr-10289 (D. Mass.)); (c) a Consent Decree of Permanent Injunction (before Judge Mark Wolf in *United States v. Gerrits, et al.*, No. 17-cv-11818 (D. Mass.)); (d) payment of damages and resolution of the *qui tam* (before Judge Indira Talwani, *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc.*, No. 13-cv-11785 (D. Mass.)); and (e) a Corporate Integrity Agreement related to the *qui tam*.

The Department of Justice received detailed information from Aegerion regarding its business performance and financial resources and ultimately determined that Aegerion could afford to pay roughly $35 million over time in fines, penalties, and damages related to the Department's multiple investigations. The SEC's investigation and settlement were separate and separately handled and negotiated; however, the Department of Justice understands from Aegerion that the criminal resolution with Aegerion was a threshold requirement for the rest of the global resolution.

ARGUMENT

The proposed sentence in the plea agreement is appropriate and satisfies the applicable factors under 18 U.S.C. § 3553, given the following considerations:

1. Aegerion's extensive cooperation with the government's ongoing criminal investigation of individuals associated with the sales and marketing of Juxtapid;

2. Aegerion's significant remedial actions, including almost complete replacement of its sales management, its executive officers, and board;

3. Aegerion's detailed admissions in its DPA with the United States regarding the existence of a conspiracy to violate HIPAA;

4. Aegerion's entry into multiple compliance and oversight agreements with Federal regulatory agencies tasked with preventing fraud and ensuring public safety;

5. Aegerion's resolution of a related, pending qui tam, the result of which will be restitution to Medicare and state Medicaid programs; and

6. Aegerion's limited financial resources.

The United States believes that the proposed sentence and its sentencing recommendation, taken in the context of the global resolution, is a reasonable and appropriate sentence. The proposed sentence effectively punishes Aegerion, prevents further wrongdoing by Aegerion, requires Aegerion not to deny that it committed the crimes of conviction, and thus provides significant general deterrence. As revised, the plea agreement addresses the Court's specific concerns regarding accountability and judicial oversight. Although the plea agreement is tendered under Rule 11(c)(1)(C), the Court has discretion over the length of probation and the standard terms of probation it deems necessary to protect the public and to promote respect for the law. *See United States v. Lewis*, 633 F.3d 262, 270 (4th Cir. 2011) ("Even if a sentencing court accepts a [C] plea agreement, the court is not bound by recommendations that are properly characterized as type B provisions.").

In deciding to plead guilty, Aegerion relied in part on the government's promise to craft a plea agreement under Rule 11(c)(1)(C) and on the certainty such an agreement provides. The government will stand by its commitment unless the defendant withdraws its proffered guilty plea. As the Fourth Circuit has stated, "a government that lives up to its commitments is the essence of

liberty under law," and "the harm generated by allowing the government to forego its plea bargain obligations is one which cannot be tolerated." *United States v. Peglera*, 33 F.3d 412, 414 (4th Cir. 1994); *see also Santobello v. New York*, 404 U.S. 257, 262 (1971) (stating "when a plea rests in any significant degree on a promise or agreement of the prosecutor, so that it can be said to be part of the inducement or consideration, such promise must be fulfilled," but noting "[a] court may reject a plea in exercise of sound judicial discretion."); *United States v. Riggs*, 287 F.3d 221, 224 (1st Cir. 2002) ("Because plea bargaining requires defendants to waive fundamental constitutional rights, we hold prosecutors engaging in plea bargaining to 'the most meticulous standards of both promise and performance.'" (quoting *United States v. Velez Carrero*, 77 F.3d 11, 11 (1st Cir. 1996)). Here, the inducement of the "C" plea for Aegerion was certainty as to the criminal penalties that would be imposed. This was a critical issue for the company to allow it to reach "global peace," that is, a comprehensive settlement of all of its outstanding liabilities to the government resulting from the sales and marketing of Juxtapid. For its part, along with the other components of the global resolution, the United States received, and continues to receive, substantial cooperation with its ongoing investigation. The government struck a bargain with Aegerion under Rule 11(c)(1)(C) and must stand by its promises. *See United States v. Cruz-Vazquez*, 841 F.3d 546, 548 (1st Cir. 2016).

Substantively, the proposed sentence ensures that the public will be protected from further illegal conduct by Aegerion related to the sales and marketing of Juxtapid. The plea agreement itself provides for significant and comprehensive compliance and oversight, including certifications of such compliance by Aegerion's current management. The incorporation of the companion DPA and Corporate Integrity Agreement into the terms of probation provides additional security that Aegerion will not repeat its crimes. The criminal fine takes into consideration the factors enumerated in 18 U.S.C. § 3572, including Aegerion's income, earning capacity, and financial resources; the relative burden of the fine; the need to deprive Aegerion of illegally obtained gains;

and the company's size and remedial measures. Moreover, based upon the Department of Justice's "ability to pay" analysis, the criminal fine and forfeiture of $7.2 million and the parallel civil settlement of $28 million represent the top end of what Aegerion could afford at the time that Aegerion agreed to the amount.

The United States therefore requests that, based on the specific facts and circumstances of this case, the Court accept the plea and impose the following sentence: a criminal fine of $6.2 million, a forfeiture of $1 million, a term of probation of three to five years on the terms specified in the plea agreement, and a mandatory special assessment of $250.[3] *See* 18 U.S.C. § 3013(a)(1)(B).

Dated: November 1, 2017

Respectfully submitted,

WILLIAM D. WEINREB
Acting United States Attorney

By: /s/Kriss Basil

Young Paik, BBO# 660896
Kriss Basil, BBO# 673074
Assistant United States Attorney
One Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3100
kriss.basil@usdoj.gov

Shannon Pedersen
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street NW, Rm 6400S
Washington, DC 20001
(202) 532-4490
Shannon.L.Pedersen@usdoj.gov

[3] Acceptance of the plea triggers Aegerion's payments in the parallel *qui tam* resolution.

CERTIFICATE OF SERVICE

I certify that I filed the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to all attorneys of record.

By: /s/Kriss Basil
Kriss Basil
Assistant United States Attorney